



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,312	08/31/2006	Francis Navarro	403504/WEINSTEIN	8215
23548 7590 06/04/2009 LEYDIG VOIT & MAYER, LTD 700 THIRTEENTH ST. NW SUITE 300 WASHINGTON, DC 20005-3960			EXAMINER SCHMIDT, EMILY LOUISE	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 06/04/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,312	Applicant(s) NAVARRO ET AL.	
	Examiner Emily Schmidt	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-15, and 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hollow part between the first and second pads identical to the hollow part in the second chamber must be shown or the feature(s) canceled from the claim(s). The hollow parts in the second chamber and between the pads do not appear to have identical shapes. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 5, 10, 14, 15, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Lynch et al. (US 2004/0044306 A1).

With regard to claim 1, Lynch et al teach an assembly fixing a catheter to a patient, comprising: a catheter including a supporting base comprising a reservoir (Fig. 3 indicated at 26) having a first end connected to a part of the catheter that is implanted in the patient (Figs. 3 and 6 end at 56) and a second end connected to at least one external tube that is in fluid communication with the catheter through the reservoir (Fig. 3 end 34 connected to tube 20 see Figs. 2 and 4), a fluid flow direction extending from the at least one external tube, through the reservoir, and to the part of the catheter implanted in the patient (Fig. 6); a housing (Fig. 3 12a); a lid closing the housing (Fig. 4 lid 14a); and a base integral to the housing and surrounding the housing, for fixation of the housing to skin of the patient (Pg. 2 [0018], wherein the housing comprises first and second chambers which communicate with each other through a passage between the first and second chambers (First chamber taken as that accommodating 16a see Figs. 3 and 7, second chamber formed in space between 14a in Fig. 4 and base generally indicated at 17a in Fig. 9), the first chamber includes a bottom wall opening through which the part of the catheter that is implanted in the patient passes (Fig. 6), the second chamber includes a bottom wall, the

Art Unit: 3767

supporting base of the catheter that includes the reservoir is accommodated partially in the passage between the first and second chambers and partially in the second chamber, the first end of the reservoir has a first end connected to the catheter is located at the first chamber in the passage and the second end of the reservoir is located in the second chamber (see Figs. 3, 6, and 9), the supporting base of the catheter includes first and second wings respectively extending, transverse to the fluid flow direction, from opposite lateral faces of the supporting base (Fig. 3 wings 28), and the lid includes, on an internal face, first and second pads generally parallel to the fluid flow direction and which, when the lid is closed, penetrate into the second chamber, respectively contact the first and second wings, and hold the supporting base of the catheter against the bottom wall of the second chamber (Fig. 4 pads are taken as members running parallel to channel 38).

With regard to claim 2, see Figs. 2, 4, and 9.

With regard to claim 5, the membrane is taken as the portion indicated at 44 (Fig. 6).

With regard to claim 10 see the hollow recess 30 (Figs. 3 and 9).

With regard to claim 14, the lid latches with members 22a (Fig. 3).

With regard to claim 15, the device is affixed to the skin (Pg. 2 [0018], incorporated reference U.S. 6,579,267 teaches adhesive is used for fixation (Col. 10 line 8).

With regard to claim 25, Lynch et al. teach an assembly fixing a catheter to a patient, comprising: a catheter including a supporting base comprising a reservoir (Fig. 3 indicated at 26) having a first end connected to a part of the catheter that is implanted in the patient (Figs. 3 and 6 end at 56) and a second end connected to at least one external tube that is in fluid communication with the catheter through the reservoir (Fig. 3 end 34 connected to tube 20 see Figs. 2 and 4), a

Art Unit: 3767

fluid flow direction extending from the at least one external tube, through the reservoir, and to the part of the catheter implanted in the patient (Fig. 6); a housing (Fig. 3 12a); a lid closing the housing (Fig. 4 lid 14a); and a base integral to the housing and surrounding the housing, for fixation of the housing to skin of the patient (Pg. 2 [0018], wherein the housing comprises first and second chambers which communicate with each other through a passage between the first and second chambers (First chamber taken as that accommodating 16a see Figs. 3 and 7, second chamber formed in space between 14a in Fig. 4 and base generally indicated at 17a in Fig. 9), the first chamber includes a bottom wall opening through which the part of the catheter that is implanted in the patient passes (Fig. 6), the second chamber includes a bottom wall, the supporting base of the catheter that includes the reservoir is accommodated partially in the passage between the first and second chambers and partially in the second chamber, the first end of the reservoir has a first end connected to the catheter is located at the first chamber in the passage and the second end of the reservoir is located in the second chamber (see Figs. 3, 6, and 9), the supporting base of the catheter includes first and second wings respectively extending, transverse to the fluid flow direction, from opposite lateral faces of the supporting base (Fig. 3 wings 28), the lid includes, on an internal face, first and second pads which penetrate into the second chamber and, when the lid is closed, the first and second pads respectively contact the first and second wings, holding the supporting base of the catheter the bottom wall of the second chamber, and hold the supporting base of the catheter bilaterally with respect to the bottom wall of the second chamber (Fig. 4 the pads are taken as the members running parallel to channel 38).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4, 9, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al. (US 2004/0044306 A1).

With regard to claims 4 and 22, Lynch et al. teach an assembly for fixing a catheter with the features substantially as claimed as in claim 1. Lynch et al. teach the passage to compliment the faces of the winged base member but Lynch et al. does not teach the passage to have oblique lateral faces which compliment the lateral faces of the supporting base. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to have a passage with oblique lateral faces because Applicant has not disclosed that such a shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the passage of Lynch et al. as it securely compliment the catheter base.

With regard to claim 9, see grooves formed on housing by 22a (Fig. 3 which compliment grooves in the lid shown in Fig. 4 to hold the external tube relative to the housing.

With regard to claim 24, Lynch et al. teaches an assembly for fixing a catheter with the features substantially as claimed. Lynch et al. does not disclose the pads and the base to have oblique lateral faces. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to use pads and a base with oblique

Art Unit: 3767

lateral faces because Applicant has not disclosed that such a shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the structures of Lynch et al. as they securely retain catheter base.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al. (US 2004/0044306 A1) as applied to claim 5 above, and further in view of Kornerup (U.S. Patent 5,685,859).

With regard to claim 6, Lynch et al. teach a catheter retention device substantially as claimed. Lynch et al. does not teach that the membrane comprises slits extending from an edge which delimits the orifice. However, Kornerup teaches a membrane which more closely surrounds the area in which a tube is inserted into the body and shows a slit (Figure 1 slit 2, Col. 5 line 16) which delimits the device. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a membrane with slits in the device of Lynch et al. because Kornerup teaches such a membrane and this would provide protection around the area in which the catheter was inserted and that in the case where the membrane would more fully cover the aperture and the area in which the tube is inserted in the that slits would be used because this would allow space to accommodate the insertion of the tube and would allow room for tubes of various sizes.

Art Unit: 3767

7. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al. (US 2004/0044306 A1) as applied to claim 5 above, and further in view of Bierman (U.S. Patent 6,428,516).

With regard to claims 11 and 12, Lynch et al. teach a catheter retention device substantially as claimed and the face of the bottom wall of the second chamber and a face of the membrane are continuous with the base of the housing (Fig. 6), Landuyt does not teach the base to include a sheet of flexible material molded with the housing or two holdfasts in the shape of human ears. However, Beirman teaches flexible anchor pad 32 (Figure 1) for securing the retainer to the patient's skin (Col. 7 lines 9-10). This pad is not disclosed to be molded with the housing however, it would have been obvious to a person of ordinary skill in the art to use a one piece construction and make the parts integral (In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)). Further, Beirman shows the pad to be in the shape of two human ears so as to provide greater stability and adhesion to the patient's skin. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to attach the device in Lynch et al. using an adhesive pad molded to the housing the shape of two human ears as taught by Bierman because it would provide greater stability.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al. (US 2004/0044306 A1) and Bierman (U.S. Patent 6,428,516) as applied to claim 12 above, and further in view of Wright et al. (US 2004/0167475 A1).

With regard to claim 13, Lynch et al. teaches a catheter retention device substantially as claimed. Lynch et al. does not disclose the housing comprising four support holdfasts in the form

Art Unit: 3767

of human ears. However, Wright et al. teaches a securement device which has a shape that can be taken to be in the shape of four human ears (Page 4 [0045] Figure 11 base 120). And further, that various shapes can be made as desired. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use four ear shaped holdfasts as opposed to two in the device of Lynch et al. because it is within the skill of one in the art to duplicate parts and such has no patentable significance (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)) and further the four holdfasts could provide a support base which better secures the base to the patient as it would provide for increased arrangement possibilities for adhering to the patient's skin, having a greater number of independently movable holdfasts, which could better conform to a variety of locations on the patient.

9. Claims 26, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al. (US 2004/0044306 A1) as applied to claims 1, 22 and 25 above, and further in view of Sorbonne (US 4,517,071).

With regard to claims 26, 27, and 29, Lynch et al. teach a catheter fixation assembly substantially as claimed. Lynch et al. does not disclose nth cover is transparent. However, Sorbonne teaches using a catheter retainer with a clear lid so as to observe the catheter and tubing (Col. 4 lines 55-56). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a transparent lid in the device of Lynch et al. because Sorbonne teaches this allows the user to observe the catheter.

Allowable Subject Matter

10. Claims 7 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claim 23 is allowed. The prior art of record does not teach or otherwise render obvious at the time the invention was made a lid which comprises pads which when the lid is closed penetrate into a chamber and are disposed on opposite sides of a part of a catheter implanted in a patient, close the chamber, and rest against the skin.

Response to Amendment

12. The amendments to the claims have been entered.

Response to Arguments

13. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3767

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767